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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,942	08/28/2003	Itzhak Bentwich	050992.0300.CPUS06	1941
37808 7590 08/03/2007 ROSETTA-GENOMICS c/o PSWS 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112			EXAMINER VIVEMORE, TRACY ANN	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 08/03/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/604,942

Applicant(s)

BENTWICH, ITZHAK

Examiner

Tracy Vivlemore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21 and 46-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 46-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 22, 2007 has been entered.

#### ***Response to arguments: Double Patenting***

Claims 21, 23, 25, 28, 29 and 32-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 10, 13, 14 and 16 of copending Application No. 10/535,164.

This provisional rejection is maintained for the reasons set forth in the office action mailed October 30, 2006.

Claims 21, 23, 25, 28, 29 and 32-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8, 11, 12 and 14 of copending Application No. 10/605,838.

This provisional rejection is maintained for the reasons set forth in the office action mailed October 30, 2006.

Furthermore, the following serial numbers of co-pending applications contain claims in which an obviousness-type double patenting rejection might be applied or contain claims for which it cannot be determined if the claimed sequences conflict:  
11/511,035 11/384,049 11/709,691 10/708,953 10/536,560 10/605,840 10/709,572  
10/709,739 11/130,649 10/604,985 10/605,923 10/707,003 10/707,147 10/707,975  
10/708,204 10/708,951 10/708,952 11/418,870 10/604,726 10/604,926 10/604,943  
10/604,945 10/604,984.

This provisional rejection is maintained for the reasons set forth in the office action mailed October 30, 2006.

In the remarks filed May 22, 2007 applicant does not address these rejections, therefore the provisional rejections stand for the reasons set forth in the office action of February 22, 2007.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent that claim 51 depends from claims 46, 48 and 50, the metes and bounds of this claim cannot be determined because 1) claim 46 recites that X is greater than Y and therefore X cannot equal Y and 2) even if claim 46 did not expressly require X be greater than Y, X and Y cannot be equal; claim 46 requires Y nucleotides of SEQ ID NO: 37405 and sets the minimum length of X as 50. Since this sequence is only 24 nucleotides in length, it is impossible to have 50 nucleotides of this sequence.

Claims 21 and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are directed to isolated nucleic acids of 18-24 or 50-120 nucleotides in length that comprise at least 18 nucleotides of SEQ ID NO: 37405, the RNA equivalent or complement of the nucleic acid or a sequence at least 62.5%, at least 75.0% or at least 83.4% identical to the sequence of at least 18 nucleotides of SEQ ID NO: 37405.

The claims encompass any nucleic acid sequence up to 120 nucleotides in length sharing at least 62.5% identity with sequences comprising at least 18 nucleotides of SEQ ID NO: 37405, a large genus of sequences defined only by a minimum identity with sequences comprising a portion of the recited SEQ ID NO. The specification discloses at paragraph 20721 that VGAM precursor 1483 produces a shorter VGAM RNA identified as SEQ ID NO: 37405. Applicant states that support for the limitations reciting percent identity with SEQ ID NO: 37405 can be found in table 2 and provides some alignments as examples. While it is acknowledged the recited SEQ ID NO appears able to bind to different target genes with varying degrees of complementarity, these examples of alignments with target genes do not demonstrate that the specification provides written description support for the claims as amended. There is nothing in the specification as filed that would convey to one of skill in the art that applicant contemplated a genus of sequences identified by the limitation reciting some minimum degree of identity with the claimed SEQ ID NO as part of the invention disclosed in the instant specification.

### ***Response to Arguments***

Applicant traverses the previous new matter rejection as it applies to the claims as amended by arguing the common structural attributes required of the claimed miR variants are disclosed in paragraphs 0118-0120 and Figure 7. Applicant asserts paragraph 0118 clearly indicates the disclosed miRNAs are capable of binding their targets with less than 100% complementarity by disclosing the sequence of miRNA may

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be partially complementary to the target binding site. It is acknowledged that paragraph 118 does refer to a nucleotide sequence of a binding site being at least partially complementary to a VGAM RNA, but the paragraphs referred to by applicant do not disclose common structural attributes of the claimed miR variants. These paragraphs describe how a binding site might be detected based on data mining of gene sequences.

Applicant further argues table 2 provides specific examples of the degree of complementarity sufficient for target site binding by the claimed miR, providing alignments where the claimed sequence binds with varying degrees of complementarity to different genes. Applicant characterizes these alignments as indicating the miRNA sequence can vary at different positions and still bind particular target binding sites. Based on this, applicant submits that one of skill would recognize applicant was in possession of a number of miRNA species with at least 62.5% complementarity between the claimed miRNA and its target mRNAs.

These arguments are not persuasive because the alignments provided by show only that the claimed sequence is capable of forming different bulged duplexes that hybridize to several different target sequences, a characteristic shared by virtually any nucleotide sequence. While applicant states this indicates the miRNA sequence can vary and still bind particular binding sites they do not demonstrate possession of any miRNA species other than the claimed sequence because they do not disclose any other species of the genus of sequence encompassed by the claims. The alignments shown by applicant provide no guidance as to which sites should be varied and how (ie,

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what the varied nucleotide should be changed to), nor what sequences can be targeted by sequences having such variations. Since the specification provides no specification guidance to the skilled artisan that sequences having particular degree of identity with the disclosed sequences are part of the invention, the specification does not provide support for the claimed genus.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has



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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
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TV  
July 31, 2007

A handwritten signature in black ink, appearing to read "Tracy Vivlemore", written in a cursive style.